

PCT

10/517101

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference RLL-266WO	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/IB 03/02186	International filing date (day/month/year) 09/06/2003	(Earliest) Priority Date (day/month/year) 07/06/2002
Applicant RANBAXY LABORATORIES LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 8 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing :

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2.  Certain claims were found unsearchable (See Box I).

3.  Unity of invention is lacking (see Box II).

## 4. With regard to the title,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

## 5. With regard to the abstract,

the text is approved as submitted by the applicant.

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

## 6. The figure of the drawings to be published with the abstract is Figure No.

as suggested by the applicant.

because the applicant failed to suggest a figure.

because this figure better characterizes the invention.

None of the figures.

## INTERNATIONAL SEARCH REPORT

**International Application No.**

PCT/IB 03/02186

A. CLASSIFICATION OF SUBJECT MATTER							
IPC 7	A61K9/24	A61K9/26	A61K9/28	A61K9/52	A61K31/4965		
A61K31/137							
According to International Patent Classification (IPC) or to both national classification and IPC							
B. FIELDS SEARCHED							
Minimum documentation searched (classification system followed by classification symbols)							
IPC 7 A61K							
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched							
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)							
EPO-Internal, WPI Data, PAJ, EMBASE, BIOSIS, MEDLINE							
C. DOCUMENTS CONSIDERED TO BE RELEVANT							
Category	Citation of document, with indication, where appropriate, of the relevant passages				Relevant to claim No.		
X	WO 99/12524 A (NYCOMED DANMARK A S ;BERTELSEN POUL (DK); SKINHOEJ ANNETTE (DK)) 18 March 1999 (1999-03-18)  example 1 claim 51 page 33, line 31 – line 35				1-9, 12, 29-35, 37-39, 68-70, 73, 76, 77		
X	US 4 713 248 A (KJORNAES KIM ET AL) 15 December 1987 (1987-12-15) cited in the application  examples 2,7 abstract				1-4, 6-9, 12, 37, 38, 68, 69, 73, 76		
					-/-		
<input checked="" type="checkbox"/>	Further documents are listed in the continuation of box C.				<input checked="" type="checkbox"/>	Patent family members are listed in annex.	
* Special categories of cited documents :							
*A* document defining the general state of the art which is not considered to be of particular relevance						*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	
*E* earlier document but published on or after the international filing date						*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)						*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.	
*O* document referring to an oral disclosure, use, exhibition or other means						*&* document member of the same patent family	
*P* document published prior to the international filing date but later than the priority date claimed							
Date of the actual completion of the international search			Date of mailing of the international search report				
9 September 2003			22 01 2004				
Name and mailing address of the ISA			Authorized officer				
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl Fax: (+31-70) 340-3016			Sindel, U				

## INTERNATIONAL SEARCH REPORT

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 783 215 A (ARWIDSSON HANS ET AL) 21 July 1998 (1998-07-21) cited in the application  claim 1 examples 1,5 -----	1,4-6,9, 13,14, 29,30, 32,33, 37,38, 68,69, 73,76
X, P	WO 03/041692 A (KARMA PHARM LTD ; SELA YORAM (IL)) 22 May 2003 (2003-05-22)  examples 1-4 claims 1,6 -----	1,4-11, 13,14, 29,30, 32,73, 108

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/IB 03/02186

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:  

Although claims 73-77 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.
2.  Claims Nos.: 1, 41 (part.), 68, 73 (part.), 82 because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  

see FURTHER INFORMATION sheet PCT/ISA/210
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-14, 18-40, 41-67 (part), 68-72, 73-77 (part), 101-103, 108-109, 114-117

#### Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box I.2

Claims Nos.: 1, 41 (part.), 68, 73 (part.), 82

Present claims 1, 41 (part.), 68, 73 (part.) and 82 relate to an extremely large number of possible compounds and products. Support within the meaning of Article 6 PCT and disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the compounds and products claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the formulations mentioned in the examples.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-14, 18-40, 41-67 (part.), 68-72, 73-77 (part.), 101-103, 108-109, 114-117

Multiple unit dosage form, each unit comprising at least one core, a first coating layer and an outer layer

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2. claims: 15-17, 41-67 (part.), 73-77 (part.), 104-107, 110-113

Multiple unit dosage form, each unit comprising at least one core, a first coating layer, one or more additional layers and an outer layer

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3. claims: 78-81, 85-100

Multiple unit dosage form, each unit comprising at least one core and a coating layer

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4. claims: 82-84

Combination drug comprising two different multiple unit dosage forms

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## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB 03/02186

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 9912524	A 18-03-1999	AT 252892 T		15-11-2003
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		WO 9912524 A1		18-03-1999
		EA 2806 B1		31-10-2002
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		JP 2001515854 T		25-09-2001
		NO 20001290 A		28-04-2000
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US 5783215	A 21-07-1998	AU 700949 B2		14-01-1999
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		JP 9502738 T		18-03-1997
		NO 960837 A		29-02-1996
		NZ 289947 A		28-07-1998
		PL 313386 A1		24-06-1996
		RU 2141822 C1		27-11-1999
		WO 9601621 A1		25-01-1996
		SK 30396 A3		10-09-1997
		TR 960034 A2		21-06-1996

INTER  ONAL SEARCH REPORT

Information on patent family members

Int  ional Application No

PCT/IB 03/02186

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US 5783215	A	TW	460300 B	21-10-2001
		ZA	9505545 A	08-01-1996
WO 03041692	A	22-05-2003	WO 03041692 A1	22-05-2003